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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/730,749

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David Angelo Tomasso

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EXAMINER

LEVKOVICH, NATALIA A

ART UNIT

PAPER NUMBER

1797

MAIL DATE

DELIVERY MODE

11/25/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/730,749	<b>Applicant(s)</b> TOMASSO ET AL.	
	<b>Examiner</b> NATALIA LEVKOVICH	<b>Art Unit</b> 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 July 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3 and 5-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3 and 5-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Response to Amendment***

1. Applicant's amendments and remarks filed on 07/20/2009 have been acknowledged.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

### ***Drawings***

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s), added by Applicant in the replacement drawings, but not mentioned in the specification: 51 and 52. Examiner also notes that the newly added element 51, supposedly representing a measurement device (such as a spectrometer) cannot be disposed as shown because the center of the apparatus accommodates slide insert mechanism 15 (Figure 3), and the specification describes the spectrometer as being located below the incubator rotor (see [0061]). Additionally, as was noted previously, the drawings must show every feature of the invention specified in the claims, as well as any structural detail that is essential for a proper understanding of the disclosed invention. Currently, the drawings do not show the following essential features recited in the amended claims: the probe tip dispenser containing probe tips, the test element holder containing cup-shaped wells, as well as the removable holder comprising immunoassay test reaction container. No new matter should be entered.

***Claim Rejections - 35 USC § 112***

4. Claims 1, 3 and 5-14 remain rejected under 35 U.S.C. 112, second paragraph, as being unclear for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, as was previously noted, the “line of travel” lacks antecedent basis, since the preceding lines of the claim do not set forth this feature. Examiner further maintains that it is unclear what structural features of the removable holder and / or test elements would allow the liquid dispense or aspirating station to act upon the test elements ‘ while the test elements are in the recess’. See MPEP § 2172.01.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 1, 3, 5-6, 10-11 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clark et al. (US 6190617).

With respect to claims 1, 10-11 and 13, Clark discloses an automated analyzer comprising, as shown in Figures 4A and 7, concentrically arranged carousels 36, 32 and 28 ['transport system', 'rotors']; stationary probe 6 ['liquid dispense or aspirating station']; probe tips 108; sample container segments 26 ['removable holders'], each having a plurality of recesses capable of holding test tubes ['test elements'], sample tubes with samples to be analyzed and / or probe tips, the recesses being arranged on the 'same line of travel' intersecting the stationary probe. The system also includes modules 69, 71 and photomultiplier tube ['measurement devices'] configured to measure chemiluminescent signals from the samples (see Figures 16 and 17). Figures 36-44 further show details of the sample container segments 600 and sample tubes 620 ['fluid supply section containing the sample to be analyzed']. The sample tubes can also be used as test elements for conducting assays, relevant reagents being added. Although the sample container segments are disclosed to hold only sample tubes 620 that contain samples, it would have been within the ordinary skill of an artisan at the time the invention was made to have employed some of the recesses in the modified segments of Clark for additionally holding test tubes ['test elements'] and probe tips, in order to reduce sample processing time by arranging the fluid handling components in a closer proximity and to gain more flexibility for conducting assays of various protocols which would allow to further diversify the tests to be performed.

Regarding claims 3 and 6, each of the carousels is capable of being employed for holding removable holders, reaction containers or reagent packs.

Referring to claim 5, Clark teaches that “the reaction vessel containing the test sample and one or more reagents is transferred to a process carousel wherein controlled environment conditions exist [‘incubator arranged in cooperation with the rotors’] (Col.16, lines 5-10).

### ***Allowable Subject Matter***

8. Claims 7-9, 12 and 14 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

The prior art does not teach, or fairly suggest an analyzer having the structure as set forth in claim 1 and further comprising waste collection containers and centrifuge modules located on the rotors, as recited in claims 7-9.

The prior art does not teach, or fairly suggest an analyzer having the structure as set forth in claim 11 and further comprising a first holder including dry-slide test elements and a second holder including an immunoassay test reaction container, as recited in claim 12, or a test element holder test strips, as recited in claim 14.

### ***Double Patenting***

9. The previous rejection of claims 1 and 3-14 under the judicially created

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doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 and 12 of a co-pending application 10/403266, has been withdrawn in view of the Terminal Disclaimer filed on 07/20/2009.

10. The previous rejection of claims 1 and 3-14 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 5-8 of application 10/436537, has been withdrawn, since the application is currently abandoned.

### ***Response to Arguments***

11. Applicant's arguments dated 07/20/2009 have been fully considered but they are moot in view of the new grounds of rejection.

### ***Conclusion***

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalia Levkovich whose telephone number is 571-272-2462. The examiner can normally be reached on Mon-Fri, 2 p.m.-10 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Jill Warden/  
Supervisory Patent Examiner, Art Unit 1797